

REMARKS

This amendment is made in response to the final Office action dated July 10, 2008. The amendment amends claim 2 to be in independent form and corrects an informality in Claim 10. Both amendments overcome objections made in the final office action and, therefore, reduce issues. It is believed that these amendments place Claims 2 and 7-10 in condition for allowance. Reconsideration is respectfully requested.

Restriction Requirement

Applicants continue to maintain the traversal of the restriction requirement for the reasons of record. This traversal also applies to newly added Claims 57-66. Upon an indication that the products of Claim 1 are allowable, the methods of using the same will not require any additional burden in examination or search and rejoinder is respectfully requested.

35 USC 112, first paragraph

Claims 1, 4, 5, 23, 24, and 49-52 have been finally rejected as failing to comply with the written description requirement. In support of the rejection, the Examiner asserts that the claims, in defining the class of products by their function and not their structure, lack sufficient written description. Applicants respectfully disagree.

The rejection emphasizes that “To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus” (emphasis omitted).

It appears to not be disputed that numerous members of the claimed genus can be identified using the methods of the invention, absent undue experimentation. It appears to also not be disputed that claim 1 presents two identifying characteristics of the claimed genus, i.e. (1) that the product is a bacteriophage and (2) that the product is lytic for *Methylobacterium*. The issue is whether **additional** characteristics are required. The problem appears to rest in whether a functional characteristic, such as (2), can be used to define the claimed isolated bacteriophage from other known bacteriophage.

Many known products and patent claims are defined primarily by their function or properties. Claims directed to antibodies that bind to a given antigen are directly analogous to the present situation and are commonplace, as discussed in detail in the last reply. Likewise issued claims are commonly directed generically to species of organisms that are also defined by their function. For example, claim 1 of U.S. 7,186,545 (**Exhibit A**) recites:

A biologically pure culture of a strain of *Lactobacillus salivarius* which is adherent to Caco-2 and HT-29 cells, and is isolated from resected and washed human gastrointestinal tract, wherein said strain of *Lactobacillus salivarius* has the following properties: a) binds to human epithelial cells and inhibits a broad range of Gram positive and Gram negative microorganisms; b) secretes a product having antimicrobial activity into a cell-free supernatant, wherein said product having antimicrobial activity is produced only by growing cells and wherein said antimicrobial activity is destroyed by proteinase K and pronase E; and c) maintains the properties of inhibiting said Gram positive and Gram negative microorganisms, and secreting said product having antimicrobial activity, in the presence of physiological concentrations of human bile and human gastric juice.

In this claim, the identifying characteristics of the genus are 1) the product is a species of *Lactobacillus* bacterium isolated from the human gastro intestinal tract and 2) the product is characterized by its activity. Another specific example is claim 13 of U.S. 6,204,006 (**Exhibit B**) that recites:

A composition comprising:

- (a) a *Pichia* strain, itself capable of producing at least 0.030 g TAPS/g *Pichia* dry weight when cultured in liquid TAPS medium for a period of 3 days at 24.degree. C. in a conical flask placed on an orbital incubator at 250 rpm, maintained in contact with a growth medium under conditions that permit recovery of TAPS; and
- (b) at least one substance that permits extraction of said TAPS from said medium.

In this claim, the identifying characteristics of the genus are 1) the product comprises a species of yeast that has undergone random mutagenesis and 2) the product is

characterized in that the mutagenized yeast has been selected for certain activity with regard to the production of TAPS.

The Examiner has made no attempt to explain why an antibody, defined primarily by what it binds, or a bacteria or yeast defined primarily by its activity, satisfies the written description requirement, but the presently claimed bacteriophage, defined by what it lyses, does not satisfy the written description requirement. Clearly, longstanding USPTO practice establishes that there is no *per se* rule against defining a class of products in large part by its function. As such, Applicants respectfully assert that *more* is required of the Examiner in this case to explain why additional characterizing features are necessary.

#### CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 251-3509.

Respectfully submitted,

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